BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

(19) Europäisches Patentamt
European Patent Office
Office européen des brev ts

(11) Publication number: 0 337 918 B1

B37

(12) EUROPEAN PATENT SPECIFICATION

(45) Date of publication of patent specification: 09.11.94 (51) Int. Cl.5: A61B 17/22

(21) Application number: 89630071.2

(22) Date of filing: 30.03.89

(54) Endarterectomy apparatus.

(30) Priority: 05.04.88 US 178029

(43) Date of publication of application:
18.10.89 Bulletin 89/42

(45) Publication of the grant of the patent:
09.11.94 Bulletin 94/45

(84) Designated Contracting States:
AT BE CH DE ES FR GB GR IT LI LU NL SE

(56) References cited:
DE-A- 2 756 427
GB-A- 1 169 419
US-A- 2 943 626
US-A- 3 372 581
US-A- 4 641 654
US-A- 4 650 466

(73) Proprietor: FOGARTY, Thomas J.
770 Welch Road
Suite 201
Palo Alto, CA 94304 (US)

(72) Inventor: Monfort, Michelle Y.
728 Brentwood Place
Los Altos California 94022 (US)
Inventor: Mollenauer, Kenneth M.
3283 Geneva Drive
Santa Clara California 95051 (US)
Inventor: Chin, Albert K.
3885 Nelson Drive
Palo Alto California 94306 (US)

(74) Representative: Schmitz, Jean-Marie et al
Dennemeyer & Associates Sàrl
P.O. Box 1502
L-1015 Luxembourg (LU)

EP 0 337 918 B1

Description

The present invention concerns an endarterectomy instrument according to the precharacterizing portion of claim 1 (see US-A-4 650 466).

This invention relates to an apparatus for shearing arteriosclerotic deposits from the lumen of an occluded artery.

The correction of arteriosclerotic deposits and occlusions has been an object of much medical research. Heretofore, correction has been achieved by cutting, stripping or compacting the deposit. See US-A-4,452,244; 4,574,781; and 4,630,609. The present invention differs markedly from the prior art in that it shears the deposit from the diseased vessel. Prior art which is material to this invention consists of US-A-2,943,626; 3,108,593; 3,108,594; 3,811,446; and 4,046,150. All relate to entrapment devices which employ wire cages for r moving objects from body passages. US-A-3,811,446 in particular discloses use of a single inexpansible wire loop for endarterectomy and a wire basket for debriding an artery. US-A-2,943,626 discloses a wire basket for the extraction of foreign bodies, but makes no suggestion of endarterectomy.

In its broadest aspects, the apparatus of the present invention comprises a selectively expansible gripper which may be inserted into an artery in a contracted condition and, once within the artery, radially expanded to grip an arteriosclerotic deposit to be removed. The apparatus enables the deposit to be sheared away from the vessel wall, without abrading the wall or damaging the artery or surrounding tissue.

One object of this invention is a decrease in complexity and duration of surgical procedures necessary to remove arteriosclerotic deposits from or bypass entirely heavily diseased arteries.

Another object of this invention is to provide an apparatus capable of shearing arteriosclerotic deposits from diseased arteries so as to leave a smoother, cleaner artery wall.

A further object of this invention is to provide a method for employing a shearing apparatus in the removal of arteriosclerotic deposits.

Other objects and aims of the invention will become clear upon further reading of the disclosure and claims.

FIG. 1 is a lateral view of one embodiment of the apparatus of the invention with parts shown in section, the shearing member expanded, and an artery being treated shown in phantom.

FIG. 2 is a cross-sectional view taken on the plane designated by line 2-2 of FIG. 1, showing the helical configuration of th expanded shearing member in an artery.

FIG. 3 is a lateral view of the apparatus in FIG. 1 showing the shearing member collapsed.

FIG. 4 is a lat ral view of another embodiment of the shearing m mber of the invention.

FIG. 5 is a partial cutaway in lateral view of an embodiment of the apparatus similar to that of FIG. 1, which additionally incorporates a shear force gauge.

FIG. 6 is a view in diametral section through an occluded artery illustrating one method of preliminary emplacement of the apparatus with respect to the artery.

FIG. 7 is a similar view illustrating another method of preliminary emplacement.

FIG. 8 is a view similar to FIG. 7 showing engagement of the shearing member with a deposit in preparation for removal of the deposit.

FIG. 9 is a view similar to FIG. 8 illustrating shearing and removal of the deposit from the artery.

The endarterectomy instrument of the present invention is defined according to the characterizing portion of claim 1.

Turning to the drawings, the preferred embodiment of the shearing apparatus is illustrated in FIG. 1. As there shown, the apparatus is disposed within a diseased artery **5** having an arteriosclerotic deposit **6** therein. The apparatus comprises a handle **10**, a grip **12**, a flexible catheter **14**, a pull cup **15**, a flexible wire **16**, and a shearing member **18**. The shearing member **18** of the preferred embodiment comprises two helically configured loops **20** and **21**, as shown in FIG. 2, although a single loop, as shown in FIG. 4, may suffice. The handle **10** is affixed to the proximal end of the wire **16** by means of a collet **11**. The collet **11** is threadably received on the handle **10** and includes a compressible annular element **9** captured in compression imparting relationship to the wire **16**. The grip **12** is affixed similarly to the proximal end of the catheter **14** by means of a collet **13** which captures an annular element **9** in compression imparting relationship to the catheter **14**. Pull cup **15** is slidably and rotatably received on the catheter **14** through means of a passage **17** extending through the cup. The loops **20** and **21** are soldered or otherwise affixed to the distal portion of wire **16** so as to leave the apical portion of the wire **16** free from and distally external to the shearing member **18**. A flexible tip **19** extends from the distal end of the wire **16** to facilitate guidance of the apparatus through narrow tortuous vessels. The loops **20** and **21** are suitably affixed at their r maining nds to th distal tip of the cath ter **14** in such a position as to comport a helical configuration. The wire **16** passes freely through the length of the cath ter **14** and is pr f rably made from spring stainless steel. The cathet r may be made of any suitabl fl xibl

polymer material. Dacron is a preferred material and polyvinyl chloride is another. A typical O.D. for the catheter is 0.12 cm (0.050 inches); a typical I.D. is 0.06 cm (0.025 inches). The shearing member may be made of 0.45 mm (0.018 inch) diameter stainless steel spring wire and, in a typical embodiment, be moveable from a contracted condition having an O.D of 0.21 cm (0.083 inches) to an expanded condition having an O.D. of 0.63 cm (0.250 inches). With the latter dimensions typical dimensions for the length of the shearing member would be 1.77 cm (0.70 inches) in the condition when the member is contracted radially and 0.76 cm (0.30 inches) when the member is expanded radially. The expanded and contracted dimensions of the shearing member will be chosen to accommodate the diameter of the artery being treated.

The spring wire of which the shearing member **18** is fabricated is preformed into an expanded helical configuration, as depicted in FIGS. 1 and 4. It is radially contracted by pushing on the handle **10** relative to the grip **12**, thereby forcing the wire **16** through the catheter **14** and extending length of the shearing member relative to the catheter's distal end, as shown in FIG. 3. Alternatively, the shearing member **18** may be radially expanded by pulling the handle **10** relative to the grip **12**, thereby diminishing the wire's length relative to the distal end of the catheter.

In the embodiment shown in FIG. 5, a grip **12a** embodying a shear force gauge **22** is substituted for the grip **12**. The shear force gauge **22** permits the monitoring of tension applied to the catheter **14** and the delivery of a preset amount of shearing force to the vessel in order to reduce potential trauma and ensure that a sufficient vessel thickness remains after removal of the deposit. The gauge **22** comprises a cup element **23** having a passage **24** through which the catheter **14** extends, a compression coil spring **25** concentrically received around the catheter **14** within the cup element and a cylindrical gauge block **26** fixed to the catheter in compression imparting relationship to the spring **25** for free rotation within the cup element **23**. The passage is sufficiently large to permit the catheter to freely rotate therein. Scale gradation indicia **27** are provided on the external surface of the block **26** for alignment with the left edge of the cup element **23**, as viewed in FIG. 5.

Pulling force is applied to the catheter **14** of the FIG. 5 embodiment by gripping the cup element **23**, as shown by the phantom line finger and thumb, designated **28** and **29**. During such pulling, th cup lement is free to turn about the longitudinal axis of the catheter and tension may be measured by observing the left edge of th cup l - m nt (as viewed in FIG. 5), relative to th indicia **27**.

FIGS. 6 - 9 illustrate the use of the apparatus of this invention in removing arteriosclerotic deposits from an artery **5**. In one embodiment of the method, as shown in FIG. 6, the artery is prepared for treatment by making an incision **40** adjacent to the arteriosclerotic deposit **6**. After incision, the apparatus is emplaced by introducing its distal end into the incision with the shearing member **18** in a radially contracted configuration. During insertion, the handle **10** may be rotated axially to reduce the torquing force of the apparatus on the artery **5** as the apparatus is introduced. Once a desired length of deposit **6** has been traversed, the shearing member **18** is radially expanded, as shown in FIG. 8, to press firmly against and engage the deposit **6** to be removed. Following this engagement, the apparatus is withdrawn, thereby shearing away that portion of the deposit **6** previously traversed, as shown in FIG. 9. Withdrawal is affected by pulling the cup **15** to engage the grip **12**, thus permitting the grip to rotate within the cup as the apparatus is withdrawn and avoiding the application of torsional forces to the apparatus.

In an alternative embodiment of the method, shown in FIG. 7, two preparatory incisions, proximal **40'** and distal **42**, are made so as to bracket that portion of the deposit **6** to be removed. The handle **10**, grip **12**, and cup **15** are then removed and the apparatus is emplaced in the artery **5** by introducing its proximal end through the distal incision **42**. Once inserted, the apparatus is threaded through the artery **6** until the proximal incision **40'** is reached, at which point the proximal end of the apparatus is passed out of the artery **5** through incision **40**. The apparatus may then be positioned as in the embodiment above until an appropriate length of deposit **6** lies between the shearing member **18** and the proximal incision **40'**. Upon placement, the handle **10**, grip **12**, and cup are reattached to the apparatus. The deposit **6** is then sheared from the artery **5** as described in the previous embodiment. The FIG. 6 and 7 methods are similar in use in that the shearing member **18** is introduced into the artery in a radially contracted condition and expanded once in place within the deposit.

It should be appreciated that the apparatus shears the section of the deposit engaged thereby from the vessel wall, as contrasted to slicing it away. Radial expansion of the helical loops is effected in such a way that the loops embed in the deposit and do not cut therethrough so as to abrade the vessel wall. The loops do not slic along the interface of the deposit and th v ssel wall, as is common in many endarterectomy apparatuses.

For an longate deposit, the process of gripping and shearing sections of th d posit and

removing them from the vessel is successively repeated until the entire length of the deposit is removed. The length of each section removed is chosen to minimize the number of times the process must be repeated, while at the same time assuring that the section may be sheared away with relative ease, without damaging the v ss l or surrounding tissue.

The process using an apparatus with a shear force gauge as shown in FIG. 5 is the same as that described above, with the addition that the gauge is monitored to detect and limit the shear force applied through the apparatus. Such monitoring may be done visually by observing the position of the indicia **27** relative to the cup **12A**. The shear force limit is chosen so as to assure that the apparatus will not injure the vessel being treated or the surrounding tissue.

Claims

1. An endarterectomy instrument comprising a flexible catheter (14) having a proximal end and an open distal end, a flexible guidewire (16) slidably extending through and protruding from the open distal end of said catheter (14) and a plaque shearing member (18) having a first end affixed to said guidewire (16) and a second end affixed to the distal end of said catheter (14), said member (18) comprising at least one flexible wire loop (20,21) and being variably expansible by longitudinal movement of said guidewire (16) relative to said catheter (14) for engaging an arteriosclerotic deposit for removal from a vessel characterized in that means (10,15) is disposed for free axial rotation relative to the flexible wire loop (20,21) to move the loop through a vessel and reduce torque on the vessel as the member moves through the vessel.

2. The endarterectomy instrument of claim 1 characterized in that the means comprises a member (15) disposed for imparting force to the proximal end of the catheter (14) and for free rotation about the longitudinal axis of the catheter (14).

3. The endarterectomy instrument of claim 1, characterized in that the flexible catheter (14) has a first handle (12a) secured to its proximal end, that the flexible guide wire (16) has affixed to its proximal end a second handle (10) that the flexible wire loop (20,21) is collapsible and that the first handle (12a) is equipped with a shear force gaug (22) to limit th force applied to the plaque shearing member (18) therethrough.

4. The endarterectomy instrument of claim 3, characteriz d in that the shear force gauge (22) comprises:

A gauge block (26) affixed to the proximal end of the catheter (14), said block (26) having gradation indicia (27) on the external surface thereof;

a member (23) slidably and rotatably received on the catheter (14) adjacent the distal end thereof, said member (23) having a portion thereof alignable with the indicia (27) on the block (26); and

a compression coil spring (25) received on the catheter (14) intermediate the gauge block (26) and member (23).

5. The endarterectomy device of claim 1 characterized in further comprising a means (22) for limiting the shearing force applied to the shearing member (18).

6. The endarterectomy device of claim 1 characterized in that the means comprises a shear force gauge (22) to limit the force applied to the shearing member (18) so as to reduce trauma to the vessel during removal of the deposit.

Patentansprüche

1. Endarterektomiegerät mit einem flexiblen Katheter (14), der ein proximales Ende und ein offenes distales Ende hat, einem flexiblen Führungsdraht (16), der sich verschiebbar durch den Katheter (14) erstreckt und aus dem offenen distalen Ende desselben hervorsteht, und einem Plaque-Abscherteil (18), das ein erstes Ende hat, welches an dem Führungsdraht (16) befestigt ist, und ein zweites Ende, das an dem distalen Ende des Katheters (14) befestigt ist, wobei das Teil (18) wenigstens eine flexible Drahtschleife (20, 21) aufweist und durch eine Längsbewegung des Führungsdrahtes (16) relativ zu dem Katheter (14) variabel aufweitbar ist, um eine arteriosklerotische Ablagerung zur Entfernung aus einem Gefäß zu erfassen, dadurch gekennzeichnet, daß eine Einrichtung (10, 15) zur freien axialen Drehung relativ zu der flexiblen Drahtschleife (20, 21) angeordnet ist, um die Schleife durch ein Gefäß zu bewegen und das auf das Gefäß ausgeübte Drehmoment zu reduzieren, wenn sich das Teil durch das Gefäß bewegt.

2. Endarterektomiegerät nach Anspruch 1, dadurch gekennzeichnet, daß die Einrichtung ein T il (15) aufweist, das so angeordnet ist, daß mit ihm ine Kraft auf das proximale End des

Katheters (14) ausgeübt werden kann und daß es um die Längsachse des Katheters (14) frei gedreht werden kann.

3. Endarterektomiegerät nach Anspruch 1, dadurch gekennzeichnet, daß der flexible Katheter (14) eine erste Handhabe (12a) hat, die an seinem proximalen Ende befestigt ist, daß an dem proximalen Ende des flexiblen Führungsdrahtes (16) eine zweite Handhabe (10) befestigt ist, daß die flexible Drahtschleife (20, 21) zusammenziehbar ist und daß die erste Handhabe (12a) mit einem Scherkraftmeßinstrument (22) ausgerüstet ist, um die Kraft zu begrenzen, die auf das Plaque-Abscherteil (18) über dieses ausgeübt wird.

4. Endarterektomiegerät nach Anspruch 3, dadurch gekennzeichnet, daß das Abscherkraftmeßinstrument (22) aufweist:
einen Meßblock (26), der an dem proximalen Ende des Katheters (14) befestigt ist, wobei der Block (26) Skalenmarkierungen (27) an seiner äußeren Oberfläche hat;
ein Teil (23), das auf dem Katheter (14) an dem distalen Ende desselben verschiebbar und drehbar aufgenommen ist, wobei das Teil (23) einen Teil hat, der mit den Skalenmarkierungen (27) auf dem Block (26) ausrichtbar ist; und
eine Druckschraubenfeder (25), die auf dem Katheter (14) zwischen dem Meßblock (26) und dem Teil (23) aufgenommen ist.

5. Endarterektomievorrichtung nach Anspruch 1, gekennzeichnet weiter durch eine Einrichtung (22) zum Begrenzen der Scherkraft, die auf das Abscherteil (18) ausgeübt wird.

6. Endarterektomievorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß die Einrichtung ein Scherkraftmeßinstrument (22) aufweist, um die Kraft zu begrenzen, die auf das Abscherteil (18) ausgeübt wird, um so eine Verletzung des Gefäßes während des Entfernens der Ablagerung zu reduzieren.

Revendications

1. Un instrument d'endartérectomie comprenant un cathéter flexible (14) ayant une extrémité proximale et une extrémité distale ouverte, un guide métallique (16) s'étendant, par glissement, à travers t faisant saillie à partir de l'extrémité distale ouv rte, dudit cathéter (14) et un organe de cisaillem nt de plaqu (18) ayant un premièr xtrémité fixée audit guide métallique (16) et un s conde xtrémité fixé à l'extrémité distale dudit cathéter (14), ledit organe (18) comprenant au moins une boucle métallique flexible (20,21) et étant extensible, de façon variable, par un mouvement longitudinal dudit guide métallique (16) par rapport audit cathéter (14), pour engager un dépôt artériosclérotique, pour l'enlèvement à partir d'un vaisseau, caractérisé en ce que un moyen (10,15) est disposé pour une libre rotation axiale, par rapport à la boucle métallique flexible (20,21) pour déplacer la boucle à travers un vaisseau et réduire la torsion, sur le vaisseau, tandis que l'organe se déplace à travers le vaisseau.

2. L'instrument d'endartérectomie de la revendication 1, caractérisé en ce que le moyen comprend un élément (15) disposé pour transmettre une force à l'extrémité proximale du cathéter (14) et pour une libre rotation autour de l'axe longitudinal du cathéter (14).

3. L'instrument d'endartérectomie de la revendication 1, caractérisé en ce que le cathéter flexible (14) a un premier manche (12a) fixé à son extrémité proximale, que le fil métallique de guidage flexible (16) a, fixé à son extrémité proximale, un second manche (10), que la boucle métallique flexible (20,21) peut être contacté et que le premier manche (12a) est équipé d'une jauge d'effort de cisaillement (22) pour limiter la force appliquée à travers l'organe de cisaillement de plaque (18).

4. L'instrument d'endartérectomie de la revendication 3, caractérisé en ce que la jauge d'effort de cisaillement (22) comprend:
un bloc de jauge (26) fixé à l'extrémité proximale du cathéter (14), ledit bloc (26) ayant un timbre imprimé de graduation (27), sur la surface extérieure de celui-ci;
un élément (23), reçu par glissement et par rotation sur le cathéter (14), adjacent à l'extrémité distale de celui-ci, ledit élément (23) ayant une portion de celui-ci alignable avec le timbre imprimé (27), sur le bloc (26); et
un ressort à boudin de compression (25) reçu sur le cathéter (14), entre le bloc de jauge (26) et l'élément (23).

5. L'appareil d'endartérectomie de la revendication 1, caractérisé en ce qu'il comprend, en outre, un moyen (22) pour limiter l' ffort d cisaillement appliqué à l'organe de cisaillement (18).

6. L'appareil d'endartérectomie de la r vendication 1, caractérisé n ce qu l moy n com-

prend une jauge d'effort de cisaillement (22), pour limiter la force appliquée à l'organe de cisaillement (18), de façon à réduire le trauma du vaisseau, durant l'enlèvement du dépôt.

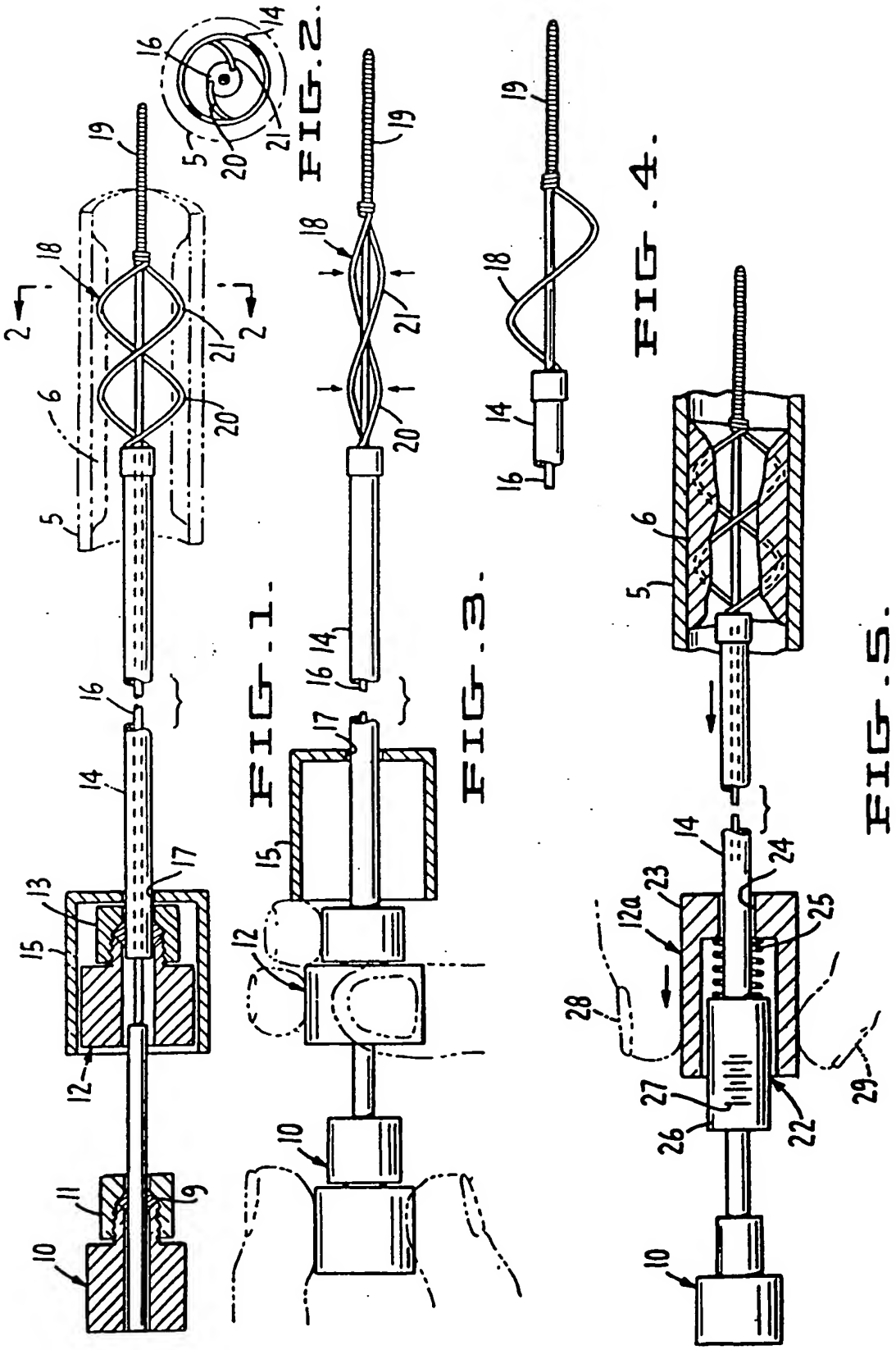
FIG. 1.
FIG. 2.
FIG. 3.
FIG. 4.
FIG. 5.

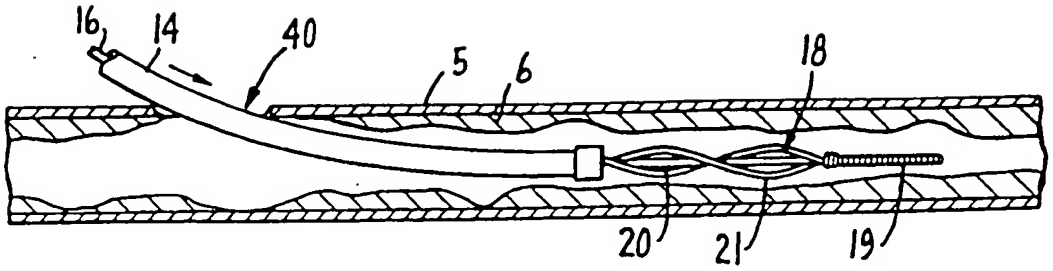

FIG. 6.

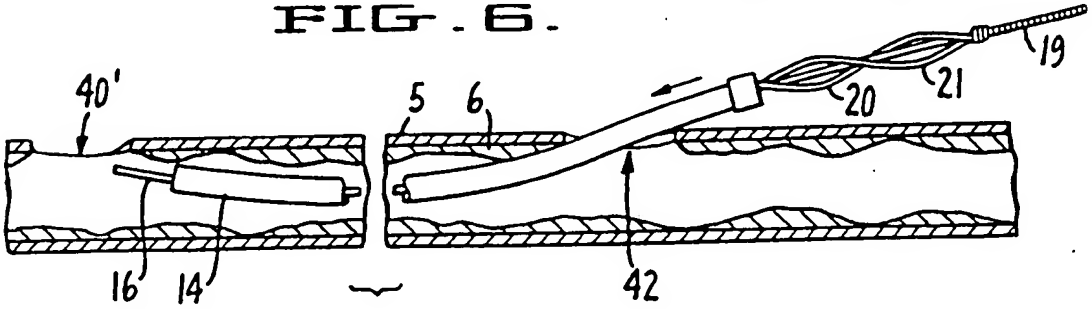

FIG. 7.

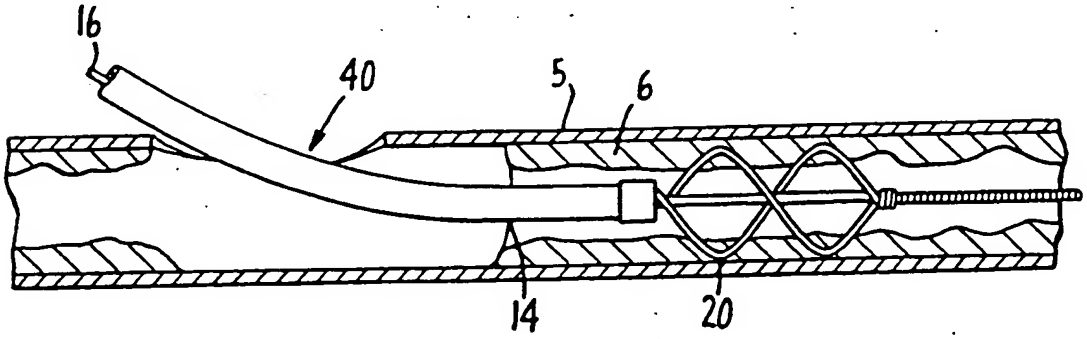

FIG. 8.

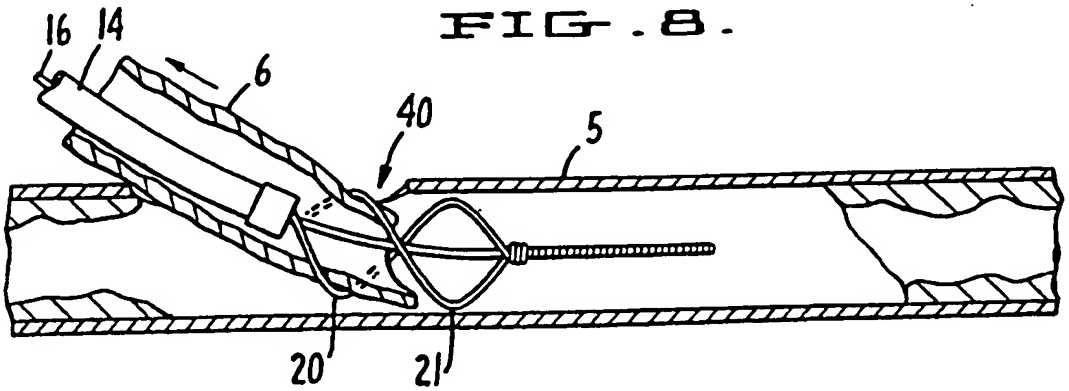

FIG. 9.